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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 112

[Docket No. APHIS-2008-0008]

RIN 0579-AD19

Viruses, Serums, Toxins, and Analogous Products; Packaging and Labeling

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; technical amendment.

SUMMARY: In a final rule published in the Federal Register on August 30, 2016, and effective on October 31, 2016, we amended the Virus-Serum-Toxin Act regulations to make veterinary biologics labeling requirements more consistent with current science and veterinary practice.

However, we inadvertently removed a requirement for an indications statement that should appear on final container labels, carton labels, and enclosures. This document corrects that error.

DATES: Effective [Insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737; (301) 851-2352.

## SUPPLEMENTARY INFORMATION:

In a final rule<sup>1</sup> that was published in the Federal Register on August 30, 2016 (81 FR 59427, Docket No. APHIS-2008-0008), and effective on October 31, 2016, we amended the Virus-Serum-Toxin Act regulations to make veterinary biologics labeling requirements more consistent with current science and veterinary practice. Among other things, in 9 CFR part 112, we amended § 112.2(a)(5) to clarify that “full instructions for the proper use of the product” refers to vaccination schedules, revaccination schedules (if necessary), indications for use, target species, recommended age for vaccination, vaccination route(s), and product license restrictions prescribed by the Animal and Plant Health Inspection Service that have a bearing on product use. However, when we made that change, we inadvertently removed a requirement for an indications statement to appear on final container labels, carton labels, and enclosures. Therefore, we are amending § 112.2(a) to re-establish the requirement for an indications statement.

### List of Subjects in 9 CFR Part 112

Animal biologics, Exports, Imports, Labeling, packaging and containers, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR part 112 as follows:

### PART 112—PACKAGING AND LABELING

1. The authority citation for part 112 continues to read as follows:

Authority: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.4.

2. Section 112.2 is amended by adding paragraph (a)(12) to read as follows:

#### § 112.2 Final container label, carton label, and enclosure.

(a) \* \* \*

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<sup>1</sup> To view the final rule and supporting documents, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0008>.

(12) An indications statement to read, “This product has been shown to be effective for the vaccination of healthy (insert name of species) \_\_\_\_ weeks of age or older against \_\_\_\_.”

Provided, That in the case of very small final container labels or carton, a statement as to where such information is to be found, such as “See enclosure for complete directions,” “Full directions on carton,” or comparable statement.

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Done in Washington, DC, this 2<sup>nd</sup> day of November 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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